REMARKS

Claim Rejections – 35 USC §102 and §103

Claims 217 and 218 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,728,159 to Stroever et al., and under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 7,048,765 to Grooms et al. Additionally, claims 217 and 218 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,033,438 to Bianchi et al. in view of U.S. Patent No. 5,728,159 to Stroever et al.

It is well established that "an invention is anticipated if the same device, including all the claim limitations, is shown in a single prior art reference. Every element of the claimed invention must be literally present, arranged as in the claim." Richardson v. Suzuki Motor Co. Ltd., 9 USPQ.2d 1913, 1920 (Fed. Cir. 1989).

Declaration of Prior Invention in the United States Under 37 C.F.R. §1.131

U.S. Patent No. 7,048,765 to Grooms et al. (hereafter "the '765 patent"), was filed on November 25, 2000 as a continuation of International PCT Application Serial No. PCT/US98/17769 filed on August 27, 1998 (hereafter "the '769 PCT application"), which in turn purports to claim priority as a continuation-in-part of U.S. Patent Application Serial No. 08/920,630 filed on August 27, 1997 (hereafter "the '630 parent application").

The subject application is a continuation of U.S. Patent Application Serial No. 10/645,413 filed on August 21, 2003, which is a divisional of U.S. Patent Application Serial No. 09/698,623 filed on October 27, 2000 (now U.S. Patent No. 6,610,065), which is in turn a divisional of U.S. Patent Application Serial No. 09/181,353 filed on October 28, 1998 (now U.S. Patent No. 6,174,311). Accordingly, the subject application has an effective priority date of October 28, 1998.

The Applicant notes that absent the purported priority claim, the asserted '765 patent to Grooms et al. does not constitute prior art to the subject application. Additionally, submitted herewith is a Declaration of Prior Invention under 37 C.F.R. §1.131 to remove the '769 PCT application as prior art to the subject application, which as indicated above was filed on August 27, 1998. The Declaration has been signed by each of the inventors and indicates that on a date prior to August 27, 1998, the Invention was conceived of and reduced

to practice in the United States. To evidence conception and reduction to practice of the Invention, attached to the Declaration is an Invention Disclosure including drawings and a description of the Invention which correspond to the subject matter disclosed and claimed in the subject patent application. The dates listed on the Invention Disclosure have been blacked out, as well as dimensional data associated with the Invention. However, the joint inventors have declared that the "Date of Conception" and the "Date Constructed" occurred prior to August 27, 1998. The Declaration also indicates that on a date prior to August 27, 1998 and shortly after the Invention was reduced to practice, the Invention was tested in the United States. The joint inventors have further declared that the "Date First Tested" listed on the Invention Disclosure occurred prior to August 27, 1998. Following construction and testing of the Invention, the Invention Disclosure was forwarded to the law firm of Woodard, Emhardt, Naughton, Moriarity & McNett for preparation of a patent application. A patent application disclosing and claiming the Invention was filed with the U.S. Patent and Trademark Office on October 28, 1998. (U.S. Patent Application Serial No. 09/181,353; issued as U.S. Patent No. 6,174,311). The subject patent application claims priority to and discloses the same subject matter as the '353 patent application filed on October 28, 1998.

The Applicant submits that the attached Declaration is effective to remove the '769 PCT application as prior art to the subject application. However, the Applicant reserves the right to refute the claim rejections set forth in the final Office Action should the Declaration for any reason be deemed ineffective to remove the '769 PCT application as prior art. The '765 patent is a continuation application filed from the '769 PCT application, which in turn purports to claim priority to the '630 parent application as a continuation-in-part application. As indicated above, absent the purported priority claim, the '765 patent does not constitute prior art to the subject application. As also indicated above, the '769 PCT application has been removed as prior art to the subject application via the filing of the Declaration of Prior Invention. Accordingly, the only subject matter which could possibly be considered to constitute prior art to the subject application is the subject matter specifically disclosed in the '630 parent application. A courtesy copy of the as-filed '630 parent application is attached hereto.

The Applicant notes that the subject matter disclosed in the '630 parent application does not include all of the subject matter which is disclosed in the '765 patent. Specifically, the '630 parent application does not include Figures 8D-8G and 9-17 and the corresponding portions of the written description, as present in the '765 patent. Accordingly, the subject matter disclosed in Figures 8D-8G and 9-17 and the corresponding portions of the written description of the '765 patent does not constitute prior art to the subject application. Specifically, the subject matter disclosed in Figures 8D-8G and 9-17 and the corresponding portions of the written description were added to the '769 PCT application, which as indicated above has been removed as prior art to the subject application via the filing of the Declaration of Prior Invention. As a result, the only subject matter which could possibly be considered to constitute prior art to the subject application is the subject matter disclosed in the '630 parent application, which disclosure is limited to Figures 1-7 and 8A-8C and the corresponding portions of the written description. However, the Applicant reserves the right to challenge the subject matter disclosed in the '630 parent application as constituting prior art to the subject application.

Amended Claims and New Claims

As an initial matter, as discussed in detail below, the Applicant has amended independent claim 217 to further distinguish over the cited references, and has amended independent claim 218 to depend from independent claim 217. Additionally, new claims 219-262 have been added to the subject application.

Independent Claim 217 and Dependent Claims 218-229

As indicate above, independent claim 217 has been rejected as being anticipated by the Stroever and Grooms references, and has also been rejected as being unpatentable over the Bianchi reference in view of Stroever.

The Applicant has amended independent claim 217 to recite, among other elements and features, "an elongate bone portion formed from a cross-sectional bone slice taken from a diaphysis of a long bone having an outer cortical bone wall surrounding an inner medullary canal", a first sidewall including "a recessed area disposed between said first and second end portions, said recessed area defined by a partial portion of the medullary canal of the long

bone and defining a concave outer surface extending . . . between said first and second end portions from said first bone engaging surface to said second bone engaging surface", and a second sidewall arranged generally opposite the first sidewall and including "a convex outer surface extending between said first and second end portions from said first bone engaging surface to said second bone engaging surface", and "wherein said concave outer surface of said first sidewall extends generally parallel with and is positioned opposite said convex outer surface of said second sidewall to provide said elongate bone portion with an elongate crescent-shaped outer cross-section in a plane including said longitudinal axis". Support for the amendments to independent claim 217 is found, for example, in paragraphs [0130], [0131] and [0174]-[0177] of the published application, in Figures 11a, 22, 47 and 48, and in as-filed claims 2, 5 and 32.

With regard to Stroever, even assuming arguendo that implant 10 could be construed as an elongate bone portion, the implant 10 does not include opposite concave and convex outer surfaces that extend generally parallel with one another "to provide said elongated bone portion with an elongate crescent-shaped outer cross-section in a plane including said longitudinal axis", as recited in independent claim 217. The implant 10 clearly does not have an elongate crescent-shaped outer cross-section, but is instead provided with a diametric or ring-shaped outer cross-section including a hollow interior region. The only implant embodiment that could arguably be described as having an elongate outer cross-section is the implant embodiment illustrated in Figures 1 and 5. However, even assuming arguendo that the implant 10 illustrated in Figures 1 and 5 could be construed as having an elongate outer cross-section, although the first side wall 14 includes a concave outer surface (i.e., the lateral outer surface designated by "L"), the implant 10 does not have an opposite second sidewall including "a convex outer surface" extending axially between the first and second end portions, as recited in independent claim 217. Notably, the sidewall of the implant 10 opposite the concave outer surface L likewise defines a concave outer surface, which is directly contrary to the recitation in independent claim 217 that the opposite second sidewall includes "a convex outer surface". Moreover, the concave outer surface L of the side wall 14 is not "generally parallel with and . . . positioned opposite" a convex outer surface, as also recited in independent claim 217.

Additionally, although Stroever appears to disclose that the implant 10 is formed from a cross-sectional bone slice taken from a long bone having an outer cortical bone wall surrounding a medullary canal, the implant 10 does not include a sidewall having "a recessed area . . . defined by a partial portion of the medullary canal of the long bone and defining a concave outer surface extending . . . between said first and second end portions from said first bone engaging surface to said second bone engaging surface", as recited in independent claim 217. Indeed, the only portion of the implant 10 which is defined by the medullary canal is the inner cavity 13. However, the inner cavity is defined by the entire medullary canal, and not "a partial portion of the medullary canal", as recited in independent claim 217. Additionally, the inner cavity 13 does not define a "concave outer surface" of the implant 10. To the contrary, the inner cavity 13 is entirely enclosed by the bone wall 14, and therefore defines inner surfaces of the implant 10, and not a "concave outer surface" of the implant, as recited in independent claim 217.

For at least the reasons set forth above, the Applicant submits that none of the implant embodiments of Stroever include each of the elements and features recited in independent claim 217, as amended. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claim 217 as being anticipated by Stroever.

With regard to Grooms, as indicated above, a Declaration of Prior Invention has been submitted herewith to remove the subject matter disclosed in Figures 8D-8G and 9-17 and the corresponding portions of the written description as prior art to the subject application. As a result, the only subject matter which could possibly be considered to constitute prior art to the subject application is the subject matter disclosed in the '630 parent application, which disclosure is limited to Figures 1-7 and 8A-8C and the corresponding portions of the written description. However, the Applicant reserves the right to challenge the subject matter disclosed in the '630 parent application as constituting prior art to the subject application.

With regard to the implant 800 illustrated in Figures 8A-8C, neither of the implant portions 801A, 801B includes a first sidewall "defining a concave outer surface extending . . . between said first and second end portions", and a second sidewall "including a convex outer surface extending . . . between said first and second end portions", and "wherein said concave outer surface of said first sidewall extends generally parallel with and is positioned opposite

said convex outer surface of said second sidewall to provide said elongate bone portion with an elongate crescent-shaped outer cross-section in a plane including said longitudinal axis", as recited in independent claim 217. Even assuming arguendo that either of the implant portions 810A, 801B illustrated in Figures 8A-8C could be construed as an elongate bone portion, the implant portions 810A, 810b do not include opposite concave and convex outer surfaces "extending . . . between said first and second end portions" which "provide said elongated bone portion with an elongate crescent-shaped outer cross-section in a plane including said longitudinal axis", as recited in independent claim 217.

Indeed, the only concave surface defined by a sidewall of the implant portions 801A, 801B is located at the far end of the implant 800, and clearly does not extend between opposite first and second end portions of the implant, as recited in independent claim 217. Similarly, the only convex surface defined by a sidewall of the implant portions 801A, 801B is located at the far end of the implant 800, and likewise does not extend between opposite first and second end portions of the implant, as recited in independent claim 217. Indeed, except for the sidewall surfaces positioned at the far ends of the implant portions 801A, 801B, the implant sidewalls that extend along a vast majority of the implant length are flat and planar, and do not define any surface that could be construed as a convex or concave surface extending between opposite first and second end portions of the implant. Additionally, the implant portions 801A, 801B clearly do not have "an elongate crescent-shaped outer cross-section", as recited in independent claim 217. To the contrary, the implant portions 801A, 801B each have a J-shaped outer cross-section, including a planar sidewall, a first end portion having a hook-shaped configuration, and an opposite second end portion including a planar flange extending perpendicularly from the planar sidewall. The Applicant submits that the J-shaped configuration of the implant portions 801A, 801B could not reasonably and fairly be construed as having "an elongate crescent-shaped outer cross-section".

Additionally, although Grooms discloses that the implant portions 801A, 801B are formed from cortical bone taken from a long bone having an outer cortical bone wall surrounding a medullary canal, neither of the implant portions 801A, 801B includes a sidewall having "a recessed area . . . defined by a partial portion of the medullary canal of the long bone and defining a concave outer surface", as recited in independent claim 217. Indeed, as

shown in Figures 8B and 8C and as described in the specification of Grooms, the implant portions 801A, 801B are formed entirely from the outer cortical bone wall, and no portion of the implant portions 801A, 801B is defined by any portion of the medullary canal. Instead, the implant portions 801A, 801B are formed entirely from a cortical bone block that is cut from cortical bone which is outwardly offset from the medullary canal. Specifically, Grooms discloses that "[a]s shown in FIG. 8B, a segment, in the form of a block or a column of cortical bone is harvested along the long axis of a long bone, such as the femur, tibia, or fibula. The shape of the bone may be inscribed into the thus-harvested cortical bone by routing, broaching or other means as described herein." (Column 13, lines 53-58). Additionally, Grooms discloses that "a device 810, such as that shown in FIGS. 8D [and] 8G is machined from bone stock as shown in FIGS. 8B, 8C". (Column 14, lines 1-3). Accordingly, no portion of the implant portions 801A, 801B is defined by any portion of the medullary canal. To the contrary, a cortical bone block is harvested from the outer cortical bone wall, and is subsequently machined to provide the implant portions 801A, 801B with the shape and configuration illustrated in Figure 8A.

For at least the reasons set forth above, the Applicant submits that none of the implant embodiments of Grooms include each of the elements and features recited in independent claim 217, as amended. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claim 217 as being anticipated by Grooms.

As indicated above, independent claim 217 has been rejected as being unpatentable over Bianchi in view of Stroever. However, as discussed above, Stroever fails to teach or suggest each of the elements and features recited in independent claim 217. Additionally, Bianchi also fails to teach or suggest each of the features recited in independent claim 217. Even assuming arguendo that the implant embodiments illustrated in Figures 8, 13, 16 and 35 could be construed as an elongate bone portion, these implant embodimetns do not include opposite concave and convex outer surfaces that extend generally parallel with one another "to provide said elongated bone portion with an elongate crescent-shaped outer cross-section in a plane including said longitudinal axis", as recited in independent claim 217.

Indeed, although each of these implant embodiments includes a bore extending through the implant body, which arguably forms a first sidewall defining a concave surface,

the sidewall opposite the concavity does not include "a convex outer surface" extending axially between first and second end portions of the implant, and wherein "said concave outer surface of said first sidewall extends generally parallel with and is positioned opposite said convex outer surface of said second sidewall". Although the threaded outer surface of the implant has a circular outer profile which arguably could be construed as defining a convex surface, the convex curvature of the threaded outer surface does not extend axially between opposite end portions of the implant body, and also does not extend "generally parallel with" the concave curvature defined by the inner surface of the through bore. First, the threaded outer surface of the implant extends linearly along the length of the implant body between opposite end portions of the implant, and therefore does not define a convex outer surface extending axially between end portions of the implant body. Furthermore, the convex curvature of the threaded outer surface extends in a direction perpendicular to the concave curvature defined by the inner surface of the through bore, and therefore does not extend "generally parallel with" the concave curvature defined by the inner surface of the through bore. Additionally, the convex curvature of the threaded outer surface does not extend generally parallel with the concave curvature defined by the inner surface of the through bore "to provide said elongate bone portion with an elongate crescent-shaped outer cross-section", as recited in independent claim 217. To the contrary, the threaded outer surface of the implant extends linearly along the length of the implant, and therefore can not fairly be said to have a crescent-shaped outer cross-section.

For at least the reasons set forth above, the Applicant submits that none of the implant embodiments of Bianchi include each of the elements and features recited in independent claim 217, as amended, whether considered along or in combination with Stroever. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claim 217 as being unpatentable over Bianchi in view of Stroever.

In summary, the Applicant submits that Stroever, Grooms and Bianchi fail to disclose or suggest each of the elements and features recited in independent claim 217, whether considered alone or in combination with one another. Accordingly, the Applicant requests withdrawal of the rejections of independent claim 217 and allowance of the same. As indicated above, independent claim 218 has been rewritten to depend from independent claim

217, and has been amended to recite additional subject matter that is supported, for example, in paragraph [0137] of the published application and in Figure 11a. Additionally, dependent claim 218 is submitted to be patentable for at least the reasons set forth above in support of the patentability of independent base claim 217.

New dependent claims 219-229 have been added to the subject application, and depend either directly or indirectly from independent base claim 217. As a result, each of the dependent claims 219-229 are submitted to be patentable for at least the reasons set forth above in support of the patentability of independent base claim 217. Additionally, support for the new dependent claims 219-229 is found, for example, in paragraphs [0130]-[0133] of the published application, in Figures 11a and 22, and in the as-filed claims 1-33.

Independent Claim 230 and Dependent Claims 231-239

The Applicant has added new independent claim 230 which recites, among other elements and features, "an elongate bone portion formed from a cross-sectional bone slice taken from a diaphysis of a long bone having an outer cortical bone wall surrounding an inner medullary canal", a first sidewall including "a recessed area disposed between said first and second end portions, said recessed area defined by a partial portion of the medullary canal of the long bone and defining a concave outer surface extending . . . between said first and second end portions from said first bone engaging surface to said second bone engaging surface", and a second sidewall arranged generally opposite the first sidewall and including "a substantially planar outer surface extending along said longitudinal axis between said first and second end portions from said first bone engaging surface to said second bone engaging surface", and "wherein said concave outer surface defined by said first sidewall is positioned opposite said substantially planar outer surface of said second sidewall relative to said longitudinal axis". Support for new independent claim 230 is found, for example, in paragraphs [0109]-[0112] and [0174]-[0177] of the published application, in Figures 1-6, 47 and 48, and in as-filed claims 2, 5 and 32.

With regard to Stroever, even assuming arguendo that the implant 10 could be construed as an elongate bone portion having a first side wall 14 including a concave outer surface (i.e., the lateral outer surface designated by "L"), the implant 10 does not have a second sidewall including "a substantially planar outer surface" extending between opposite

end portions of the implant, and with the concave outer surface of the first sidewall "positioned opposite said substantially planar outer surface of said second sidewall". Notably, the sidewall of the implant 10 opposite the concave outer surface L defines another concave outer surface, and not a substantially planar outer surface, as recited in independent claim 230. The Applicant also notes that the outer implant surfaces illustrated in Figure 1 which are designated as references "L" and "M" are symmetrical to one another. Due to this symmetry, one of these surfaces can not be construed as a concave outer surface and the other a substantially planar outer surface. Indeed, the only outer surface of the implant 10 that is arguably substantially planar is the anterior outer surface A illustrated in Figures 1 and 5. However, the anterior outer surface A does not extend "axially along a length" of the implant 10, as recited in independent claim 230, but instead extends laterally across a width of the implant between the lateral and medial outer surfaces L and M. Furthermore, the posterior outer surface P opposite the anterior outer surface A is not concave, as required by independent claim 230. Instead, the posterior outer surface P appears to comprise a convex outer surface.

Additionally, as indicated above with regard to independent claim 217, although Stroever appears to disclose that the implant 10 is formed from a cross-sectional bone slice taken from a long bone, the implant 10 does not include a sidewall having "a recessed area . . . defined by a partial portion of the medullary canal of the long bone and defining a concave outer surface extending . . . between said first and second end portions from said first bone engaging surface to said second bone engaging surface", as recited in independent claim 230. Indeed, the only portion of the implant 10 which is defined by the medullary canal is the inner cavity 13. However, the inner cavity 13 is defined by the entire medullary canal, and not "a partial portion of the medullary canal", as recited in independent claim 230. Additionally, the inner cavity 13 does not define a "concave outer surface" of the implant 10. To the contrary, the inner cavity 13 is entirely enclosed by the bone wall 14, and therefore defines inner surfaces of the implant 10. Therefore, the inner cavity 13 does not define a "concave outer surface" of the implant, as recited in independent claim 230.

For at least the reasons set forth above, the Applicant submits that none of the implant embodiments of Stroever include each of the elements and features recited in independent claim 230.

With regard to Grooms, in view of the Declaration of Prior Invention submitted herewith, the only subject matter which could possibly be considered to constitute prior art to the subject application is the subject matter disclosed in the '630 parent application, which disclosure is limited to Figures 1-7 and 8A-8C and the corresponding portions of the written description. With regard to the implant 800 illustrated in Figures 8A-8C, neither of the implant portions 801A, 801B includes a first sidewall "defining a concave outer surface extending . . . between said first and second end portions", and a second sidewall arranged generally opposite the first sidewall and including "a substantially planar outer surface extending along said longitudinal axis between said first and second end portions from said first bone engaging surface to said second bone engaging surface", and "wherein said concave outer surface defined by said first sidewall is positioned opposite said substantially planar outer surface of said second sidewall relative to said longitudinal axis", as recited in independent claim 230. Indeed, the only concave surface defined by a sidewall of the implant portions 801A, 801B is located at the far end of the implant 800, and clearly does not extend between opposite first and second end portions of the implant, as recited in independent claim 230. Additionally, although a mid-portion of the outer surface of the implant portions 801A, 801B appears to be substantially planar, the concave surface defined by the first sidewall is not positioned opposite "a substantially planar outer surface of said second sidewall relative to said longitudinal axis", as recited in independent claim 230.

Additionally, as indicated above with regard to independent claim 217, although Grooms discloses that the implant portions 801A, 801B are formed from cortical bone taken from a long bone, the implant portions 801A, 801B do not include a sidewall having "a recessed area . . . defined by a partial portion of the medullary canal of the long bone and defining a concave outer surface", as recited in independent claim 230. Indeed, as shown in Figures 8B and 8C and as described in the specification of Grooms, the implant portions 801A, 801B are formed entirely from the outer cortical bone wall, and no portion of the implant portions 801A, 801B is defined by any portion of the medullary canal. Instead, the

implant portions 801A, 801B are formed entirely from a cortical bone block that is outwardly offset from the medullary canal.

For at least the reasons set forth above, the Applicant submits that none of the implant embodiments of Grooms include each of the elements and features recited in independent claim 230.

With regard to Bianchi, this reference also fails to teach or suggest each of the features recited in independent claim 230. Even assuming arguendo that the implant embodiments illustrated in Figures 8, 13, 16 and 35 could be construed as an elongate bone portion, none of these implant embodiments includes a first sidewall "defining a concave outer surface extending . . . between said first and second end portions", and a second sidewall arranged generally opposite the first sidewall and including "a substantially planar outer surface extending along said longitudinal axis between said first and second end portions from said first bone engaging surface to said second bone engaging surface", and "wherein said concave outer surface defined by said first sidewall is positioned opposite said substantially planar outer surface of said second sidewall relative to said longitudinal axis", as recited in independent claim 230. Indeed, although each of these implant embodiments includes a bore extending through the implant body which arguably forms a first sidewall defining a concave surface, the sidewall opposite the concavity does not include "a substantially planar outer surface extending along said longitudinal axis between said first and second end portions from said first bone engaging surface to said second bone engaging surface". To the contrary, the threaded outer surface of the implant opposite the concave surface defined by the through bore has a circular outer profile, and therefore could not reasonably and fairly be said to comprise "a substantially planar outer surface".

For at least the reasons set forth above, the Applicant submits that none of the implant embodiments of Bianchi include each of the elements and features recited in independent claim 230.

In summary, the Applicant submits that Stroever, Grooms and Bianchi fail to disclose or suggest each of the elements and features recited in independent claim 230, whether considered alone or in combination with one another. Accordingly, the Applicant requests allowance of independent claim 230. New dependent claims 231-239 have been added to the

subject application, and depend either directly or indirectly from independent base claim 230. As a result, each of the dependent claims 231-239 are submitted to be patentable for at least the reasons set forth above in support of the patentability of independent base claim 230. Additionally, support for the new dependent claims 231-239 is found, for example, in paragraphs [0109]-[0112] of the published application, in Figures 1-6, and in the as-filed claims 1-33.

Independent Claims 240 and 245 and Dependent Claims 241-244 and 246-249

The Applicant has added new independent claims 240 and 245 to the subject application, with each of these independent claims being directed to a method of forming a spinal implant, and which recite, among other elements and features, "providing a long bone having a diaphysis", "removing a cross-sectional bone slice from the diaphysis of the long bone, the cross-sectional bone slice including an outer cortical bone wall surrounding an inner medullary canal having a length", "cutting the bone slice along the length of the medullary canal and dividing the bone slice into a plurality of bone slice segments, with each of the bone slice segments including a partial portion of the outer cortical bone wall and a partial portion of the medullary canal", and "forming the spinal implant of claim 217/230 from one of the plurality of bone slice segments, with the recessed area of the first sidewall defined by the partial portion of the medullary canal". Support for new independent claims 240 and 245 is found, for example, in paragraphs [0174]-[0177] of the published application, in Figures 44-48, and in as-filed claims 2, 5 and 32.

With regard to Stroever, as indicated above, the implant 10 does not include each of the elements and features recited in independent claims 217 and 230. Accordingly, Stroever likewise fails to teach the step of "forming the spinal implant" of claims 217 and 230 from one of the plurality of bone slice segments, as recited in independent claims 240 and 245, respectively. Additionally, although Stroever appears to disclose that the implant 10 is formed from a cross-sectional bone slice taken from a long bone, Stroever fails to disclose or suggest the step of "cutting the bone slice along the length of the medullary canal and dividing the bone slice into a plurality of bone slice segments, with each of the bone slice segments including a partial portion of the outer cortical bone wall and a partial portion of the medullary canal". To the contrary, the implants 10 disclosed in Stroever are formed from the

entire bone slice, and there is no indication or suggestion that the bone slices are in any way cut along the length of the medullary canal to divide the bone slice into a plurality of bone slice segments that each include a partial portion of the outer cortical bone wall and a partial portion of the medullary canal. Moreover, the only portion of the implant 10 that is defined by the medullary canal is the inner cavity 13. However, the inner cavity is defined by the entire medullary canal. Therefore, a recessed area of the implant 10 is not "defined by [a] partial portion of the medullary canal", as recited in independent claims 240 and 245. For at least the reasons set forth above, the Applicant submits that Stroever fails to teach each of the elements and features recited in independent claims 240 and 245.

With regard to Grooms, as indicated above with regard to independent claims 217 and 230, the implant portions 801A, 801B do not include each of the elements and features recited in independent claims 217 and 230. Accordingly, Grooms likewise fails to teach the step of "forming the spinal implant" of claims 217 and 230 from one of the plurality of bone slice segments, as recited in independent claims 240 and 245, respectively. Additionally, although Grooms discloses that the implant portions 801A, 801B are formed from cortical bone taken from a long bone, Grooms fails to disclose or suggest the step of "dividing the bone slice into a plurality of bone slice segments, with each of the bone slice segments including a partial portion of the outer cortical bone wall and a partial portion of the medullary canal". To the contrary, as shown in Figures 8B and 8C and as described in the specification of Grooms, the implant portions 801A, 801B are formed from cortical bone blocks cut entirely from the outer cortical bone wall, with no portion of the cortical bone blocks including a partial portion of the medullary canal. Instead, the cortical bone blocks are taken from cortical bone that is outwardly offset from the medullary canal. Similarly, the implant portions 801A, 801B formed from the cortical bone blocks do not include "a recessed area of the first sidewall defined by the partial portion of the medullary canal", as recited in independent claims 240 and 245. Indeed, the only portion of the implant 10 which is defined by the medullary canal is the inner cavity 13. However, the inner cavity is defined by the entire medullary canal. Therefore, a recessed area of the implant 10 is not "defined by [a] partial portion of the medullary canal", as recited in independent claims 240 and 245. For at least the reasons set

forth above, the Applicant submits that Grooms fails to teach each of the elements and features recited in independent claims 240 and 245.

With regard to Bianchi, as indicated above with regard to independent claims 217 and 230, none of the implant embodiments include each of the elements and features recited in independent claims 217 and 230. Accordingly, Bianchi likewise fails to teach the step of "forming the spinal implant" of claims 217 and 230 from one of the plurality of bone slice segments, as recited in independent claims 240 and 245, respectively. Additionally, although Bianchi discloses that the implant embodiments may be formed from cortical bone, Bianchi fails to disclose or suggest the step of cutting a bone slice along a length of the medullary canal and "dividing the bone slice into a plurality of bone slice segments, with each of the bone slice segments including a partial portion of the outer cortical bone wall and a partial portion of the medullary canal". For at least the reasons set forth above, the Applicant submits that Bianchi fails to teach each of the elements and features recited in independent claims 240 and 245, whether considered alone or in combination with any of the other cited references.

New dependent claims 241-244 have been added to the subject application and depend either directly or indirectly from independent base claim 240, and new dependent claims 246-249 have been added to the subject application and depend either directly or indirectly from independent base claim 245. As a result, each of the dependent claims 241-244 and 246-249 are submitted to be patentable for at least the reasons set forth above in support of the patentability of their respective independent base claims 240 and 245. Additionally, support for the new dependent claims 241-244 and 246-249 is found, for example, in paragraphs [0174]-[0177] of the published application, in Figures 44-48, and in as-filed claims 2, 5 and 32.

Independent Claim 250 and Dependent Claims 251-262

The Applicant has added new independent claim 250 to the subject application, which is directed to a method of forming a spinal implant, and which recites, among other elements and features, "providing a long bone having a diaphysis", "removing a cross-sectional bone slice from the diaphysis of the long bone, the cross-sectional bone slice including an outer cortical bone wall surrounding an inner medullary canal having a length", "cutting the bone

slice along the length of the medullary canal and dividing the bone slice into a plurality of bone slice segments, with each of the bone slice segments including a partial portion of the outer cortical bone wall and a partial portion of the medullary canal", and "forming an elongate bone portion from one of the plurality of bone slice segments", with the elongate bone portion including, among other elements and features, "a first sidewall extending between the first and second bone engaging surfaces and including a recessed area . . . defined by the partial portion of the medullary canal and defining a concave outer surface extending along the longitudinal axis between the first and second end portions from the first bone engaging surface to the second bone engaging surface". Support for new independent claim 250 is found, for example, in paragraphs [0174]-[0177] of the published application, in Figures 44-48, and in as-filed claims 2, 5 and 32.

The Applicant notes that the steps recited in independent claims 250 of "providing a long bone having a diaphysis", "removing a cross-sectional bone slice from the diaphysis of the long bone" and "cutting the bone slice along the length of the medullary canal and dividing the bone slice into a plurality of bone slice segments, with each of the bone slice segments including a partial portion of the outer cortical bone wall and a partial portion of the medullary canal" are also recited in independent claims 240 and 245. Accordingly, independent claim 250 is submitted to be patentable over Stoever, Grooms and Bianchi for reasons similar to those set forth above in support of the patentability of independent claims 240 and 245.

Additionally, with regard to Stroever, as indicated above with regard to independent claims 217 and 230, although Stroever appears to disclose that the implant 10 is formed from a cross-sectional bone slice taken from a long bone having an outer cortical bone wall surrounding a medullary canal, the implant 10 does not include a sidewall having "a recessed area . . . defined by [a] partial portion of the medullary canal" which defines "a concave outer surface extending . . . between said first and second end portions from said first bone engaging surface to said second bone engaging surface", as recited in independent claim 250. Indeed, the only portion of the implant 10 which is defined by the medullary canal is the inner cavity 13. However, the inner cavity is defined by the entire medullary canal, and not a "partial portion of the medullary canal", as recited in independent claim 250. Additionally, the inner

cavity 13 does not define a "concave outer surface" of the implant 10. To the contrary, the inner cavity 13 is entirely enclosed by the bone wall 14, and therefore defines inner surfaces of the implant 10, and not a "concave outer surface" of the implant, as recited in independent claim 250.

With regard to Grooms, as also indicated above with regard to independent claim 217 and 230, although Grooms discloses that the implant portions 801A, 801B are formed from cortical bone taken from a long bone having an outer cortical bone wall surrounding a medullary canal, the implant portions 801A, 801B do not include a sidewall having "a recessed area . . . defined by [a] partial portion of the medullary canal" which defines "a concave outer surface extending . . . between said first and second end portions" of the implant, as recited in independent claim 250. Indeed, as shown in Figures 8B and 8C and as described in the specification of Grooms, the implant portions 801A, 801B are formed entirely from the outer cortical bone wall, and no portion of the implant portions 801A, 801B is defined by any portion of the medullary canal. Instead, the implant portions 801A, 801B are formed entirely from a cortical bone block that is outwardly offset from the medullary canal.

New dependent claims 251-262 have been added to the subject application and depend either directly or indirectly from independent base claim 250. As a result, each of the dependent claims 251-262 are submitted to be patentable for at least the reasons set forth above in support of the patentability of independent base claim 250. Support for the new dependent claims 251-254 is found, for example, in paragraphs [0174]-[0177] of the published application, in Figures 44-48, and in as-filed claims 2, 5 and 32. Additionally, support for new dependent claims 255-262 is found, for example, in paragraphs [0109]-[0112] and [0130]-[0133] of the published application, in Figures 1-6, 11a and 22, and in the as-filed claims 1-33.

CONCLUSION

The Applicant respectfully requests entry of this response to the final Office Action and consideration and allowance of the present application including pending claims 217-262. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

By: _____

Brad A. Schepers
Reg. No. 45,431
Krieg DeVault LLP
One Indiana Square, Suite 2800
Indianapolis, Indiana 46204-2079
(317) 238-6334 (voice)
(317) 238-6371 (facsimile)